K021112

CONFIDENTIAL

NOV 22 2002

Section 16. 510(k) Summary

Section 16.a Date Summary Prepared

01 March 2002

Section 16.b Company Information

Establishment:

eVent Medical Ltd.,
6a Liosban Business Park
Tuam Road
Galway, Ireland

Official Correspondent:

Mike Griffiths
CEO
eVent Medical Ltd.,
800 Grand Avenue, Suite C-3
Carlsbad, CA 92008
760 497-3553
760-434-1334 (Fax)

Section 16.c Name of Device

Proprietary:	*Inspiration* ™ Ventilator System
Common/Usual:	Respiratory Ventilator
Classification:	Continuous Ventilator (§868.5895/73CBK)

Section 16.d Equivalent Devices

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for predicate devices and the *Inspiration* ™ Ventilator System, as well as testing to accepted industry standards. The predicate devices are as follows:

1. Servo Ventilator 300, Siemens-Elema AB, K960010
2. 760 Ventilator, Puritan Bennett Inc., K984379

Section 16.e Device Description

The *Inspiration*™ Ventilator System is housed in a metallic enclosure, comprising clear anodized aluminum with painted finish and is mounted on a mobile stand. User controls and display screen are located on the front face of the Ventilator. Display and controls operation is described in the *Ventilator Settings and Controls* section of the User Manual (See Section 14 of this Submission). Ventilation parameters are programmed by the operator, using the function and navigation keys plus the *Push & Turn* control device on the Ventilator front panel, in conjunction with selectable display screens.

The programmed data from the User Interface is processed by the main microprocessor and stored in ventilator non-volatile memory. The microprocessor uses the stored data in the control of breath delivery.

Oxygen and air supply connections are located on the back of the Ventilator. The patient breathing circuit connection is located below the front face of the unit, together with a pneumatic outlet for driving an optional accessory jet nebulizer. The Ventilator stand serves to support the main Ventilator unit, breathing circuit tubing and accessory equipment, facilitating connection to the Ventilator.

The *Inspiration*$_{TM}$ Ventilator System incorporates three communications interfaces, namely, a Nurse Call interface, an RS-232 and an Ethernet interface. The Nurse Call interface comprises normally open and normally closed relay contacts (changeover switch) acting simultaneously with an alarm condition. Both the RS232 and Ethernet interfaces enable the same data transmission to receiving terminals such as nurse and physician workstations and PC equipment.

Section 16.f Intended Use

The *Inspiration* ™ Ventilator System is intended for use with a wide range of patients from infant through adult, requiring respiratory support for a wide range of clinical conditions in hospital, hospital-type facilities and intra-hospital transport.

The intended use, patient population and environment of use are the **same** or similar to the predicate devices, the Servo Ventilator 300, Siemens-Elema AB and the 760 Ventilator, Puritan Bennett Inc.

Section 16.g Technological Characteristics

The *Inspiration*$_{TM}$ Ventilator System provides continuous ventilation to patients requiring respiratory support by means of pressure-based and volume-based mandatory and spontaneous breaths. The system operates on AC, internal battery, or external battery power and includes an integral compressor. This enables the system to operate both in the hospital environment and also during intra-hospital transport.

Ventilation modes are selected using the display screens and associated controls. The following ventilation modes are available:

Volume-based synchronized mandatory ventilation; V-CMV.

Volume-based synchronized intermittent mandatory ventilation; V-SIMV

Pressure-based synchronized mandatory ventilation; P-CMV

Pressure-based synchronized intermittent mandatory ventilation; P-SIMV

Spontaneous ventilation; SPONT

Pressure support; PSV

The User Manual, Section 14 of this submission, describes the procedures for selecting individual modes, plus performance specifications. Please refer to sections 3.2, 3.3, 8.5 of the User Manual.

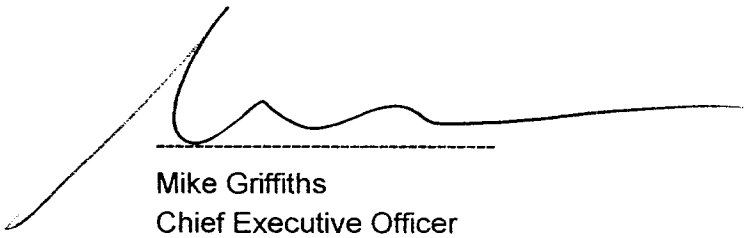
The *Inspiration*$_{TM}$ Ventilator System consists of two major systems, the pneumatic system and the electrical/electronic system, which combine under software control to deliver respiratory support at operator-determined parameters. The pneumatic system, under microprocessor control, supplies air and oxygen to the patient system, external to the device. The electrical/electronic system inputs and supervises one of three alternative power sources to the unit and provides electronic control of the ventilator's pneumatic system components.

The *Inspiration*$_{TM}$ Ventilator System can operate with a range of standard ventilator accessories, such as breathing circuits, nebulizer and humidifier.

Section 16.h Certification Statement

In accordance with the requirements of 21 CFR 807.87(j), the following certification is provided:

eVent Medical believes that all data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.



Mike Griffiths
Chief Executive Officer
eVent Medical Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2002

Mr. Mike Griffiths
Chief Executive Officer
eVent Medical Limited
800 Grand Avenue, Suite C3
Carlsbad, California 92008

Re: K021112
Trade/Device Name: Inspiration™ Ventilator System
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: August 20, 2002
Received: August 26, 2002

Dear Mr. Griffiths:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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2.g INDICATIONS FOR USE STATEMENT

Applicant: eVent Medical Ltd

510(k) Number: K021112

Device Name: *Inspiration*$_{TM}$ Ventilator System

Indications for Use: The *Inspiration*$_{TM}$ Ventilator System is indicated for use with a wide range of patients from infant through adult, requiring respiratory support for a wide range of clinical conditions in hospital, hospital-type facilities and intra-hospital transport.

Prescription Use: Yes (Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K021112

Prescription Use ✓ or OTC Use _____